Long-term adverse effects of extracorporeal shock-wave lithotripsy for nephrolithiasis and ureterolithiasis: a systematic review

Fankhauser, Christian D ; Kranzbühler, Benedikt ; Poyet, Cédric ; Hermanns, Thomas ; Sulser, Tullio ; Steurer, Johann

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Fankhauser CD, Kranzbühler B, Poyet C, Hermanns T, Sulser T, Steurer J

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This study presents a systematic review of the published literature on possible long-term adverse effects after extracorporeal shock wave lithotripsy (ESWL). While published disagreement exists, this review finds that previous evidence supporting an association between ESWL and long-term adverse effects is weak, and that the majority of studies show no evidence for any increase in post-ESWL incidence of arterial hypertension (24 of 30 studies), diabetes mellitus (4 of 6 studies), kidney dysfunction (14 of 14 studies), or infertility (2 of 2 studies). Currently, no strong evidence exists to support the hypothesis that ESWL causes long-term adverse effects.

Introduction

Extracorporeal shock wave lithotripsy (ESWL) is a noninvasive treatment option for nephro- and ureterolithiasis. Since its introduction in the 1980s, millions of patients have benefited, and ESWL quickly became the gold standard therapy for nephro- and ureterolithiasis. Known short-term side effects of ESWL are renal hematoma, infectious complications, "steinstrasse" ("stone street") blockage caused by remaining stone fragments, renal colic, or regrowth of urinary calculi.[1] However, long-term adverse effects (LAE) have not been thoroughly evaluated to date, and several authors have reported contradictory results. Potential LAE of ESWL include arterial hypertension (HTN), diabetes mellitus (DM), chronic kidney disease (CKD), and decreased fertility (FERT). Because no large prospective studies have been conducted to observe LAE after ESWL, we synthesize the published evidence regarding the four most discussed LAE in this systematic review.

Methods

This systematic review was conducted in accordance with the recommendations of the PRISMA statement[2] and a recent publication about reporting adverse events in systematic reviews.[3]

Literature search

We conducted a literature search on December 19, 2013 using the following databases: Embase, Scopus, Cochrane, Medline, and Web of Science. For our literature research we used combinations of search terms related to "hypertension," "diabetes mellitus," "kidney function

deterioration," fertility," and "adverse effects," in various combinations with "long-term," "nephro- and ureterolithiasis," and "lithotripsy." The detailed search strategy used to query the Medline database is shown in Appendix 1. Additionally, the reference lists of all of the identified publications were searched manually to identify further relevant studies describing long-term adverse effects of ESWL.

Eligibility criteria

Peer-reviewed studies reporting at least one of the four adverse effects of interest (HTN, DM, CKD, FERT) were eligible for inclusion in this review. We excluded studies with fewer than 30 patients and those with a follow-up period of less than one year.

Study selection

Duplicate articles were filtered using the "close match function" within the Endnote citation management software and subsequently two authors (CDF, BK) performed additional manual deduplication. The same two authors screened the titles and abstracts independently to select publications compliant with the eligibility criteria and came to a consensus about inclusion of studies.

Data extraction and synthesis

A data extraction sheet (based on the data extraction template from the Cochrane Consumers and Communication Review Group) was developed and further adapted after pilot testing on five randomly selected eligible studies. Data were collected on study design, length of follow-up, patient characteristics, outcome assessment methods, and outcome definitions for HTN, DM, CKD, and FERT. One investigator (CDF) extracted the data and a second investigator (BK) reviewed the extracted data. Disagreements were discussed and resolved by consensus or by third-party arbitration (JS).

Quality assessment

Study quality was determined using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist for cohort studies and randomized controlled trials.[4] Overall study quality and bias risk were rated according to the SIGN recommendations. Quality ratings were assigned as follows: high, indicating that most criteria were fulfilled and the study conclusions are very unlikely to be altered; moderate, that some criteria were fulfilled and, in cases where the criteria were not fulfilled, the study conclusions are unlikely to be altered; and low, that few or no of the criteria were fulfilled, and conclusions are likely to be altered.

Results

Study selection

The complete study selection process is illustrated in Figure 1. After deduplication, we retrieved 889 citations. Of these, 827 studies were discarded after review of the abstracts because they did not fulfill the eligibility criteria. The full text of 62 publications was reviewed in detail, and a final total of 39 studies matched the inclusion criteria.

Study characteristics

The selected studies were published between 1988 and 2013. Two were randomized controlled trials (RCT) and 37 were cohort studies. The number of patients included ranged from 30 to 1758 in the ESWL study groups. Trial and patient characteristics are summarized in Appendix 2.

Quality of the included studies

The SIGN quality was rated high in 3 studies (8%), moderate in 9 studies (23%), and poor in 27 studies (69%). A detailed summary of the assessment is reported in Appendix 3.

Outcomes of primary interest

Arterial hypertension (HTN)

Of the 30 included studies reporting on the incidence of HTN after ESWL, two were RCTs and 28 were cohort studies. All were published between 1988 and 2012. The number of patients treated with ESWL in each study ranged from 35 to 1758, and median follow-up periods ranged from 12 to 240 months. We found 17 studies describing patients with HTN without any comparison to a control group. Two studies compared the HTN prevalence with a healthy population, whereas the remaining 11 studies matched the ESWL-treated patients with an untreated nephro-/ureterolithiasis population. We identified 10 different blood pressure cut-off levels used to define HTN. In 6 out of 30 studies, the authors concluded that ESWL might be causal for new-onset HTN. No evidence for an increase in the incidence of HTN was reported in the remaining 24 (80%) publications (see Fig. 2). Data were not pooled in a meta-analysis because of heterogeneous definitions of HTN and data acquisition. For individual study results, see Appendix 2, Tables 1 and 2.

Diabetes mellitus (DM)

All six included studies were cohort studies, which were published between 2008 and 2013. The number of ESWL-treated patients ranged from 70 to 772. Four studies incorporated a control group, whereas two describe only a single ESWL cohort. One study retrieved information from an epidemiological register, two studies assessed serum glucose levels, and three studies asked physicians or patients about a potential diagnosis of DM and prescribed anti-diabetic therapy. Follow-up periods ranged from 5 to 20 years. In two studies, the authors concluded that ESWL might be causal for new-onset DM, whereas four studies found no evidence for an increase in the incidence of DM. Due to heterogeneous control groups and use of different methods to obtain the DM status of the patients, study data were not pooled in a meta-analysis. For individual study results, see Appendix 2, Tables 3 and 4.

Chronic kidney disease (CKD)

Of the 14 included studies regarding kidney failure, we retrieved seven retrospective and seven prospective cohort studies, which were published between 1992 and 2012. Median follow-up periods ranged from 15 months to 17 years. One study compared the ESWL cohort with a cohort treated with percutaneous-nephrolithotomy (PNL), whereas another study compared patients with ESWL-treated renal stones to patients with ESWL-treated ureteral stones. One study compared patients with ESWL-treated stones to a cohort of asymptomatic stone carriers. Eleven studies had no control groups. Eleven studies retrieved information about kidney function by looking at laboratory findings, one study by asking the patient about any kidney problems, and two studies did not report precisely how kidney function was assessed. All 14 studies concluded that there is no evidence for an increase in the incidence of CKD after ESWL. Due to the heterogeneous methods used to obtain the patients' kidney function status and varied definitions of kidney function, data were not pooled in a meta-analysis. For individual study results, see Appendix 2, Table 5.

Decreased fertility (FERT)

We were able to identify two retrospective studies focusing on female infertility but none focusing on male infertility. Vieweg[5] asked 67 women about secondary sterility, contraception, miscarriages, and malformations in their newborns. Of the 67 female patients who answered the questionnaire, only 10 patients were actually trying to conceive after ESWL. Similarly, Erturk[6] sent out a questionnaire to 39 patients, of which ten mothers reported to have successfully delivered 11 babies in total. For individual study results see Appendix 2, Table 6.

Discussion

From animal studies, in vitro studies, and imaging studies, we have evidence that ESWL can cause histological renal changes, even at low doses, and that it may result in an increase in mean arterial blood pressure by damaging the kidney[7,8] and other intra-abdominal organs.[9] Uncertainty prevails regarding long-term adverse effects.

Arterial hypertension (HTN)

While treating renal calculi with ESWL, the kidneys are directly exposed to shockwaves. Shockwaves cause shear stress on the urinary calculi, but as a potential side effect, shockwaves might also damage kidney tissue and could therefore lead to HTN.

In our review, only six out of 30 studies concluded that ESWL might lead to HTN. Of these six studies, three had no controls or comparison of ESWL-treated patients with an average population. A study by Krambeck et al. found an ESWL-related increase in HTN rate in 2006[10] but the authors subsequently published the results of a study focusing on a different cohort with an incidence of HTN not different compared to persons without prior ESWL.[11] While comparing PNL and ESWL, Lingeman et al. found a lower annual incidence of HTN among ESWL patients compared to non-ESWL patients, yet also reported a rise in diastolic blood pressure.[12] The evidence presented in the six cohort studies that found an increased new-onset HTN rate after ESWL is weaker compared to that in the other 24 studies, including two RCTs, which found no association (see Appendix 2, Tables 1 and 2).

A systematic review with a meta-analysis regarding the incidence of HTN after ESWL was published recently by Yu.[13] Despite stating an intention to follow the PRISMA guidelines, no literature research protocol was published, and it seems that the search was performed with very few key words. Perhaps due to our extended research protocol, our study included 19 additional studies compared to the set evaluated by Yu.[13] In contrast to the approach taken by

Yu,[13] we waived a meta-analysis because we detected two common pitfalls affecting most of the included studies. First, variation in the definition of HTN cut-off values can change the annualized incidence rate of HTN from 6% to 14%.[14] We note that in the included studies a total of 10 different blood pressure cut-off levels were used to define HTN. Second, the data sources and methods used to obtain blood pressure reading or diagnostic codes were very heterogeneous. In our opinion, the above-described heterogeneity in both the definitions of HTN and the methods to obtain the HTN status make a meta-analysis unadvisable.

Diabetes mellitus (DM)

The pancreas lies in the retroperitoneum and might be exposed to shockwaves with resulting tissue damage during ESWL due to its proximity to the kidneys. Two studies indicated an increase in DM rate after ESWL. The first study, by Kazemi et al., found an 8.1% diabetes prevalence after ESWL in a cohort of 307 patients[15]. This prevalence has to be interpreted with caution because no control group was observed. Thus, it remains possible that some metabolic dysfunction resulting in nephro- and ureterolithiasis and DM might result in the higher DM prevalence, rather than the ESWL therapy itself[16]. The second study, published by Krambeck et al in 2006,[10] describes a 16.8% incidence of new-onset DM after ESWL, but the authors subsequently published the results of a study focusing on a different cohort with an incidence of DM not different compared to persons without prior ESWL.[17] With only six relevant studies, none of them RCT, it is not possible to make a conclusive statement about whether ESWL might cause DM.

Chronic kidney disease (CKD)

The kidneys are directly exposed to shockwaves when urinary calculi lie within the renal pelvis. Short-term adverse effects after ESWL have been described in detail.[1] However, it is unclear whether the observed acute tissue damage may lead to chronic kidney function deterioration. None of the studies that we reviewed found evidence for an increase in the

incidence of kidney function deterioration after ESWL. Therefore, based on the existing evidence, we conclude that ESWL is not seen to influence kidney function in a negative manner. However, the current literature is limited and therefore cannot give a final statement about possible association of ESWL with kidney failure.

Fertility (FERT)

The uteri/adnexa, their vascular supply, and the vascular supply of the testicles are directly exposed to shockwaves when urinary calculi lie in the distal ureter, therefore raising the question of whether ESWL may compromise male or female fertility. In a systematic review including clinical short term studies, in vitro studies, and animal studies, Philippou et al.[18] could not provide a final statement about male infertility as no studies with long-term follow-up were available at the time. In our current literature research, we identified two studies[5,6] focusing on female fertility. In both studies, only 10 patients had attempted to become pregnant, which is an insufficient sample size to show any effect of ESWL on fertility. Furthermore, fertility is difficult to define and to assess in a retrospective manner. Therefore, no conclusion about the possible influence of ESWL on fertility can be drawn from the identified studies.

Limitations

The poor methodological quality of the published studies may result in bias. For example, the vast majority of the included studies are retrospective studies, which are prone to bias. Furthermore, most studies do not compare the incidence of LAE between the ESWL patients and an adequate control group. Our search criteria were designed and reviewed by clinicians and librarians and were included in our peer-reviewed protocol. However, it is possible that not all potentially relevant studies were identified due to undetected flaws in our search strategy, and thus this would have to be classified as a potential source of bias.

Conclusions

Currently, no strong evidence supports the hypothesis that ESWL causes long-term adverse effects. Most of the relevant studies from the published literature have to be interpreted with caution because study designs are mostly retrospective, with inadequate control groups, small sample sizes, and short follow-up periods. New studies addressing the above-mentioned weaknesses are needed to reach a final conclusion about long-term adverse effects after ESWL.

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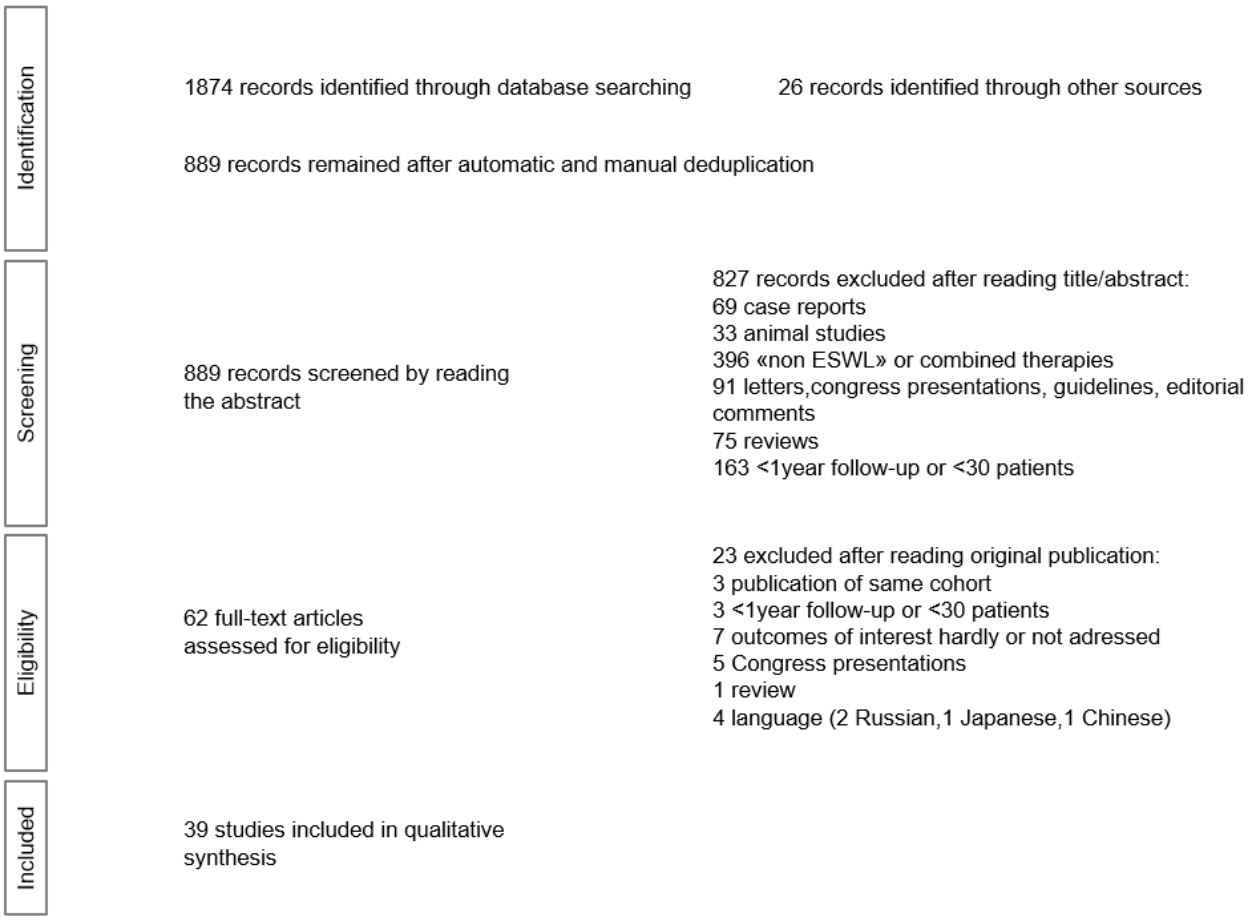

Figure 1: Selection of extracorporeal shock wave lithotripsy (ESWL) studies. From the initial 889 records that we initially identified, we included 39 studies after the selection process, as illustrated above.

Appendix 2

Table 1 **Studies suggesting no association between ESWL and an increase in the incidence of arterial hypertension**

First Author	Study design	Follow-up time in months (mean or median)	Control group	Identification of patients with arterial hypertension pre= before ESWL post= after ESWL	Definition of arterial hypertension	Results/ Conclusion
Liedel [1]	Retrospective cohort	40	Other group of patients treated with ESWL	Pre: chart review Post: patient reported	RR >160/95 mmHg or prescribed antihypertensive therapy	No evidence for an ESWL-related increased risk of hypertension; no indication for any deterioration of renal function
Montgomery [2]	Retrospective cohort	29 (SD 8.4) (range 12-44)	None	Pre: chart review Post: Reported by physicians	Systolic RR > age+100 mmHg, diastolic RR >95mmHg	No change in the mean arterial pressure
Nijman [3]	Prospective cohort	24 (range 13-40)	None	Not reported	Not reported	Hypertension did not occur in any patient during follow-up
Puppo [4]	Retrospective cohort	average not reported (range 12-36)	None	Pre: chart review Post: reported by physician	RR > 130/95 mmHg for women, >140/90 mmHg for men younger 45y and >150/95 mmHg older 45y	No evidence for an increase in the incidence of arterial hypertension
Mays [5]	Prospective cohort	24	PNL	Post: Reported by patients	Not reported	new medical problem (…) which could be potentially been associated with their renal treatment was found 3% in the PNL, and in 2% in the ESWL

						group
Yokoyama [6]	Retrospective cohort	18 (SD 17)	None	Pre: chart review Post: Not reported	RR >160/95 mmHg	No evidence for an increase in the incidence of arterial hypertension
Zanetti [7]	Prospective cohort	29	None	Pre: measured by physician Post: measured by physician	RR >160/95 mmHg	No evidence for an increase in the incidence of arterial hypertension
Carlson [8]	Retrospective cohort	40 (range 12-56)	PNL	Pre: chart review Post: measured by physician	Not reported	No evidence for an increase in the incidence of arterial hypertension
Claro [9]	Prospective cohort	22 (range 5-41)	None	Pre: measured by physicians Post: measured by physicians	Diastolic RR >90mmHg	No evidence for an increase in the incidence of arterial hypertension
Simon [10]	Retrospective cohort	24	None	Pre: measured by physicians Post: telephone interview with patient or physician	Not reported	No evidence for an increase in the incidence of arterial hypertension
Sarica [11]	Prospective cohort	33 (range 30-39)	None	Pre: measured by physicians Post: measured by physician	Not reported	No evidence for an increase in the incidence of arterial hypertension
Jewett [12]	RCT	12	asymptomatic stone carriers	Pre: measured by physicians Post: measured by physicians	Diastolic RR >100mmHg	No evidence for an increase in the incidence of arterial hypertension

Appendix 2

Author	Study Question	Comparable groups	Accural rate	Outcome at time of enrolment	Drop outs	Comp. lost to follow-up	Definition of outcomes	Blind assessment	Missing blinding addressed	Reliability	External validity and reliability	Number of assessements	Confounder analysis	Confidence intervals	Bias/confounding overall	Effect is real?	Targeted groups?
Barbosa [1]	Y	N	NA	N	73 %	NA	Y	NA	NA	NA	N	N	N	N	-	N	Y
Brinkmann [2]	Y	NA	NA	Y	16 %	N	Y	NA	Y	Y	N	N	N	N	-	Y	Y
Carlson [3]	Y	N	NA	Y	45 %	N	Y	NA	NA	NA	N	N	N	N	-	Y	Y
Chew [4]	Y	N	N	Y	42 .7 %	NA	Y	NA	NA	N	N	N	N	N	-	Y	Y
Claro [5]	Y	Y	N	Y	16 %	N	Y	NA	NA	Y	Y	Y	N	N	+	Y	Y
Cogain [6]	Y	Y	NA	Y	N A	NA	Y	NA	NA	NA	NA	N	N	N	+	Y	Y
Eassa [7]	Y	NA	N	Y	16 %	N	Y	NA	NA	Y	NA	N	N	N	+	Y	Y
El-Assmy [8]	Y	NA	N	Y	47 %	NA	N	NA	NA	Y	N	N	N	N	-	Y	Y
El-Assmy [9]	Y	NA	N	Y	31 %	N	N	NA	NA	Y	N	N	N	N	-	Y	Y
El-Nahas [10]	Y	NA	N	Y	30 %	N	Y	NA	NA	N	N	N	N	N	-	Y	Y
Erturk [11]	Y	NA	N	N	44 %	N	N	NA	NA	N	N	N	N	N	-	N	Y
Graff [12]	Y	NA	N	N	43 %	N	N	NA	NA	N	N	N	N	N	-	Y	Y

Janetschek [13]	Y	NA	N	Y	25 %	N	Y	NA	NA	Y	N	N	N	N	-	Y	Y
Kazemi [14]	Y	NA	Y	Y	78 %	N	Y	NA	NA	Y	Y	N	N	N	-	Y	Y
Knapp [15]	Y	NA	N	Y	0 %	NA	Y	NA	NA	Y	Y	N	N	N	+	Y	Y
Krambeck [16]	Y	Y	Y	Y	41 %	Y	Y	NA	NA	Y	N	N	Y	Y	+	Y	Y
Krambeck [17]	Y	Y	NA	Y	NA	NA	Y	NA	NA	NA	NA	N	N	Y	+	Y	Y
Lingeman [18]	Y	Y	Y	Y	27 %	N	Y	NA	NA	Y	Y	Y	Y	Y	+	Y	Y
Liedl [19]	Y	N	N	N	35.4 %	N	Y	NA	NA	N	Y	N	N	N	-	N	Y
Mays [20]	Y	N	NA	N	45 %	N	N	N	N	Y	N	Y	N	N	-	N	Y
Montgomery [21]	Y	NA	NA	Y	22 %	N	Y	NA	NA	N	N	N	N	Y	-	N	Y
Nijman [22]	Y	NA	N	NA	0 %	N	N	NA	NA	N	N	N	N	N	-	N	Y
Perry [23]	Y	NA	N	N	54 %	N	N	NA	NA	N	N	N	Y	N	-	N	Y
Puppo [24]	Y	NA	N	Y	0 %	NA	Y	NA	NA	N	N	N	N	N	-	N	Y
Protogerou [25]	Y	NA	N	Y	0 %	N	Y	N	N	Y	Y	Y	N	N	++	Y	Y
Ramakrishnan [26]	Y	NA	N	Y	0 %	N	N	NA	NA	N	N	N	N	N	-	Y	Y
Sarica [27]	Y	NA	N	Y	0 %	N	Y	NA	NA	Y	N	N	N	N	-	N	Y
Sato [28]	Y	Y	Y	Y	70 %	N	Y	NA	NA	N	N	N	Y	Y	+	Y	Y
Simon [29]	Y	NA	NA	N	5 %	N	Y	NA	NA	N	N	N	N	N	-	N	Y

Strohmaier [30]	Y	Y	N	Y	0 %	N	Y	N	N	Y	Y	Y	N	N	+	Y	Y
Traxer [31]	Y	NA	N	Y	0 %	N	N	NA	NA	N	N	N	N	N	-	N	Y
Vieweg [32]	Y	NA	NA	N	20 %	N	N	NA	NA	N	N	N	N	N	-	N	Y
Williams [33]	Y	NA	NA	Y	39 %	N	Y	NA	NA	Y	N	N	N	N	-	N	Y
Yokoyama [34]	Y	NA	N	Y	0 %	N	Y	NA	NA	Y	N	N	N	N	-	N	Y
Yoo [35]	Y	Y	Y	Y	0 %	N	Y	N	N	Y	Y	N	N	N	-	Y	Y
Zanetti [36]	Y	NA	N	Y	28 %	N	Y	NA	NA	Y	Y	N	N	N	-	Y	Y
Zanetti [37]	Y	NA	N	Y	0 %	NA	Y	NA	NA	N	N	Y	N	N	-	N	Y

Table 1: Study quality determined using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist for cohort studies

	Research question adequate	Assignment is randomized	Adequate concealment method	Blinding	Similar treatment and control	Treatment is only difference	Standard, valid and reliable	Drop outs	Intention to treat analysis	Multicenter analysis	Risk of bias or confounding	overall effect is due to the study	Applicable to the patient group
Elves [38]	Y	CS	N	NA	Y	Y	Y	12%	N	NA	++	Y	Y
Jewett [39]	Y	CS	N	NA	Y	Y	Y	0%	N	NA	++	Y	Y

Table 2: Study quality was determined using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist for randomized controlled trials

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Traxer [13]	Prospective cohort	Mean not reported (range 6-96)	None	Not reported	Not reported	No evidence for an increase in the incidence of arterial hypertension
Elves [14]	RCT	26 (range 12-60)	asymptomatic stone carriers	Pre: measured by physicians Post: measured by physician	systolic RR >160mmHg or diastolic RR > 90mmHg	No evidence for an increase in the incidence of arterial hypertension
Strohmaier [15]	Prospective cohort	24	Only ureteral stones	Pre: measured by physicians Post: measured by physicians	Not reported	"No difference between renal and uretheral stones, or between the ESWL treatment and the other groups"
Brinkmann [16]	Prospective cohort	45	None	Pre: measured by physicians Post: measured by physicians	Not reported	No evidence for an increase in the incidence of arterial hypertension
Protogeru [17]	Prospective cohort	12	Distal ureteral stones treated with ESWL, or URS	Pre: 24h RR measurement Post: 24h RR measurement	Mean 24h RR value > 125/80 mmHg	"ESWL may be responsible for a drop in blood pressure"
Ramakrishnan [18]	Prospective cohort	90	None	Pre: measured by physicians Post: measured by physicians	Not reported	1 of 39 children developed arterial hypertension
Eassa [19]	Prospective cohort	43 (SD 13) (range 18-57)	None	Pre: measured by physicians/ reported by patients Post: measured by physicians/ reported by patients	RR >140/90 mmHg or prescribed antihypertensive therapy	No evidence for an increase in the incidence of arterial hypertension

El-Assmy [20]	Retrospective cohort	45 (SD 42) (range 12-192)	None	Pre: measured by physicians Post: measured by physicians	Not reported	No evidence for an increase in the incidence of arterial hypertension
Sato [21]	Retrospective cohort	204 (range 132-264)	Ureteral stones treated with ESWL	Patient reported	Diagnosis of arterial hypertension and prescribed antihypertensive therapy	No evidence for an increase in the incidence of arterial hypertension
Chew [22]	Retrospective cohort	240	Canadian community health survey	Post: reported by patients	Diagnosis of arterial hypertension and prescribed antihypertensive therapy	No evidence for an increase in the incidence of arterial hypertension
Krambeck [23]	Retrospective cohort	104 (range 4-300)	Non surgically managed urolithiasis patients	Based on ICD entries of patients in database	Not reported	Failed to identify an association between ESWL and HTN
El Nahas [24]	Retrospective cohort	62 (SD 43) (range 25-210)	None	Pre: measured by physicians Post: measured by physicians	Diastolic RR > 95 centile	No evidence for an increase in the incidence of arterial hypertension

Table 2 Studies suggesting an association between ESWL and an increase in the incidence of arterial hypertension

First Author	Study design	Follow-up time in months (mean or median)	Control group	Identification of patients with arterial hypertension pre= before ESWL post= after ESWL	Definition of arterial hypertension	Results/ Conclusion by authors
Williams [25]	Retrospective cohort	17-21	None	Pre: chart review Post: Reported by physicians	RR > 150/95 mmHg	Statistical increase in diastolic and systolic blood pressure after ESWL "8% of patients developed hypertension"
Lingemann [26]	Retrospective cohort	96 (SD 9)	PNL, URS	Pre: chart review Post: Reported by physicians	prescribed antihypertensive therapy or diastolic RR >90mmhg	Statistically significant rise in diastolic blood pressure; but no evidence in the increase of the incidence of arterial hypertension
Knapp [27]	Prospective cohort	mean not reported (range 17-23)	None	Pre: Measured by physicians Post: Measured by physicians	RR >145/95mmhg	Compared with normal prevalence of arterial hypertension in Austria (…) the risk of risk of hypertension is increased in older patients
Janetschek [28]	Prospective cohort	26 (range 18-31)	None	Post: Measured by physicians	systolic RR >140 mmhg and/or diastolic RR >90 mmhg	There is some evidence that in patients older than 60 years ESWL is associated with new onset of arterial hypertension
Krambeck [29]	Retrospective cohort	228	Non surgically managed	Post: Reported by	Diagnosis of arterial hypertension and prescribed	New onset hypertension 36.4% in the ESWL compared to 27.4% in the control group

			urolithiasis patients	patients	antihypertensive therapy	ESWL is associated with the development of HTN
Barbosa [30]	Retrospective cohort	72	Normal Population from NHANES database	Post: Reported by patients	Diagnosis of arterial hypertension and prescribed antihypertensive therapy	The prevalence of arterial hypertension in the ESWL group increased from 26.7% before to 37.8% after ESWL compared to a matched control group 28% before and 32.5% after ESWL ESWL is associated with the development of HTN

Table 3 Studies suggesting no association between ESWL and an increase in the incidence of diabetes mellitus

First Author	Design	Follow-up time in months (mean or median)	Reference group	Identification of patients with diabetes mellitus pre= before ESWL post= after ESWL	Results/ Conclusion by authors
Sato [21]	Retrospective cohort	204 (range 132-264)	Ureteral stones treated with ESWL	reported by patients	No evidence for an increase in the incidence of diabetes mellitus
Chew [22]	Retrospective cohort	240	Canadian community health survey	reported by patients	No evidence for an increase in the incidence of diabetes mellitus
Cogain [31]	Retrospective cohort	104 (range 36-276)	Non-SWL urolithiasis patients	Post: disease codes from an epidemiological	No evidence for an increase in the incidence of diabetes mellitus

				register	
El-Nahas [24]	Retrospective cohort	62.4 (SD 43) (range 25-210)	None	Post: Blood serum glucose levels	No evidence for an increase in the incidence of diabetes mellitus

Table 4 **Studies suggesting an association between ESWL and an increase in the incidence of diabetes mellitus**

First Author	Design	Follow-up time in months (mean or median)	Reference group	Identification of patients with diabetes mellitus pre= before ESWL post= after ESWL	Results/ Conclusion by authors
Krambeck [29]	Retrospective cohort	228	Non surgically managed urolithiasis patients	Post: Patient reported	New onset was noted in 16.8 % in eswl and 6.6% in the control group
Kazemi [32]	Retrospective cohort	median not reported (range 180-228)	None	Pre: medical chart review Post: Blood serum glucose levels, diagnosis of diabetes and prescribed anti-diabetic therapy	Evidence that ESWL might be associated with an increase in fasting blood sugar levels

Table 5 Studies suggesting no association between ESWL and an increase in the incidence of chronic kidney disease (CKD)

First Author	Design	Follow-up time in months (mean or median)	Reference group	Identification of patients with KFD pre= before ESWL post= after ESWL	Definition of KFD status	Results/ Conclusion by authors
Graff [33]	Prospective cohort	19 (range 12-26)	None	Not reported	Not reported	During follow-up complete restoration was observed. Serious complications during follow-up were no encountered.
Mays [5]	Prospective cohort	24	PNL	Post: Reported by patients	Not reported	No evidence for an increase in the incidence of kidney function deterioration after ESWL compared to the PNL group
Zanetti [34]	Prospective cohort	15 (range 12-24)	None	Pre: Reported by physicians Post: Reported by physicians	Ultrasound and blood serum creatinine levels	No evidence for an increase in the incidence of kidney function deterioration after ESWL
Simon [10]	Retrospective cohort	24	None	Post: Reported by physicians	Blood serum creatinine	No evidence for an increase in the incidence of kidney function deterioration after ESWL
Sarica [11]	Prospective cohort	33 (range 30-39)	None	Post: Ultrasound and laboratory values	Kidney size and parenchymal thickness	“The long-term evaluation of our children proved the safety of this procedure”
Traxer [13]	Prospective cohort	mean not reported (range 6-96)	None	Not reported	Blood serum creatinine and parenchymal	No parenchymal lesions were observed; values for serum creatinine levels were not

					damage	reported.
Perry [35]	Retrospective cohort	21	None	Not reported	Blood serum creatinine	No evidence for an increase in the incidence of kidney function deterioration after ESWL
Brinkmann [16]	Prospective cohort	45	None2	Pre: measured by physicians Post: measured by physicians	Blood serum creatinine levels, kidney size measured by ultrasound	No evidence for a damage to growing kidneys
El-Assmy [36]	Retrospective cohort	90 (SD 52)	None	Not reported	Not reported	No evidence for an increase in the incidence of kidney function deterioration after ESWL
El-Assmy [20]	Retrospective cohort	46 (SD 42) (range 12-192)	None	Post: measured by physicians	Blood serum creatinine	No evidence for an increase in the incidence of kidney function deterioration after ESWL "Safe in the long run"
Eassa [19]	Prospective cohort	Mean 44 (SD 14) (range 18-57)	None	Post: measured by physicians	Blood serum creatinine	No significant long-term effects on renal function
Sato [21]	Retrospective cohort	204 (range 132-264)	Ureteral stones treated with ESWL	Pre: reported by patients Post: reported by patients	Reporting hemodialysis	No evidence for an increase in the incidence of kidney function deterioration after ESWL
El-Nahas [24]	Retrospective cohort	62 (SD 43) (range 25-210)	None	measured by physicians	Not reported	no evidence for retardation of renal growth
Yoo [37]	Retrospective cohort	20 (SD 13)	Non-ESWL treated urolithiasis patients	Pre: measured by physicians Post: measured by physicians	Blood serum creatinine	ESWL is associated with delayed deterioration of renal function in patients with a preexisting decrease in kidney function

Table 6 **Studies suggesting no association between ESWL and an increase in the incidence of infertility**

First Author	Design	Follow-up time in months (mean or median)	Reference group	Identification of patients with Fertility Status pre= before ESWL post= after ESWL	Results/ Conclusion by authors
Vieweg [38]	Retrospective cohort	38 (range 9-68)	None	Patient reported	No evidence for an increase in the incidence of infertility
Erturk [39]	Prospective cohort	Not reported	None	Patient reported	No evidence for an increase in the incidence of infertility

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